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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/971,344	11/17/97	GOELET P	04990.0008-2

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EXAMINER	
SISSON,B	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 11/23/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/971,344	Philip Goelet et al.
Examiner	**Group Art Unit**
Bradley L. Sisson	1634

☒ Responsive to communication(s) filed on *13 Oct 1998*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *34-39, 42-44, and 47-53* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *34-39, 42-44, and 47-53* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Specification

1. The incorporation of essential material in the specification by reference to a foreign application or patent, to a publication, or to abandoned US patent applications is improper. At page 34, line 5, USSN 08/005,061 has been incorporated by reference as disclosing preferred embodiment. Said USSN 08/005,061 is abandoned. While one may incorporate essential subject matter that is found in published US patents, non-issued applications, including abandoned applications, must be brought into the specification of the subject application. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Rejections - 35 USC § 112

2. Claims 34-39, 42-44, and 47-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. The claimed methods are drawn to (i) analysis of human DNA wherein at least two single nucleotide polymorphisms (SNPs) are selected are selected, amplified, and compared to reference nucleotides; and (ii) the method of (i) further limited in that the SNPs co-segregate with a genetic trait and is predictive that the human exhibits the trait.

It is clear for the specification that the application is directed primarily to the analysis of equine nucleic acid sequences, and SNPs found therein. More specifically, the specification has been found to contain 6 examples. Examples 1-5 are directed in their entirety to the analysis of equine sequences; e.g., Example 1 (pages 45-47), Discovery of Equine Polymorphisms; Example 2 (pages 47-50), Characterization of Equine Polymorphisms; Example 3 (pages 50-57), Allelic Frequency Analysis of Equine Polymorphisms in Small Population Studies; Example 4 (page 55) Equine Parentage Testing; and Example 5 (pages 56-58), Equine Identity Testing. The one and only example that is related to the claimed method is found in Example 6 (pages 58-62): Analysis of Human SNP. Upon closer inspection of Example 6, it is clear that the portion of the example directed to "False Error Report" (pages 61-62) has nothing to do with any human SNP, but rather, is a review of an equine study.

The method requires the comparison of at least two identified SNPs. Claim 47, places no restriction on just how close, or how far apart these SNP need to be from one another. In fact, as presently worded, the method encompasses two SNPs that occur on different chromosomes. Further, the method encompasses the analysis of mutations that have yet to be discovered. Clearly, the specification cannot adequately describe nor enable that which has yet to be discovered yet applicant

seeks to dominate future discoveries. At best, applicant can only describe that which is known to same at the time the application was filed. The specification teaches numerous aspects of equine study and analysis, not human. The claimed method, unfortunately is completely drawn to the analysis of human SNPs. The specification does not identify the SNPs, nor the traits that are associated therewith.

As set forth in the prior Office action, if the specification does not identify the reaction conditions nor provide the starting materials, it would require undue experimentation for one of skill in the art most closely associated with the invention at the time the invention was made, to practice the invention. *See Genentech Inc. v. Novo Nordisk A/S* 42 USPQ2d 1001 (CAFC 1997).

It is well settled that "[i]n cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970). The area of chemical art to which the claimed invention belongs is highly unpredictable. The human genome has not been sequenced yet the claimed method encompasses SNPs which could occur in any part of the human genome. Differences in racial and ethnic groups present added levels of unpredictability, yet the specification provides no guidance as to how the skilled artisan may appropriately address such issues.

At page 6 of the response received 13 October 1998, hereinafter the response, it is asserted that "[t]he methods needed to practice the claimed invention are well known to those of skill in the art and are routinely performed in a manner consistent with the present invention. Therefore, the

Examiner's rejection is improper and should be withdrawn." Such assertions, unfortunately, place an unreasonable reliance upon the skill of the ordinary artisan to provide the enabling disclosure. As reproduced in the prior Office action, and for convenience if reproduced *infra*:

> [2] It is true, as Genentech argues, that a specification need not disclose what is well known in the art. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate written description. (*Genentech.* Emphasis added)

The specification provides starting materials and reaction conditions for analysis of EQUINE SNPs, not the analysis of SNPs from any other source, including human. The bold statements contained in the specification that the disclosure is somehow enabling for the analysis of SNPs from "any plant or animal" (specification at page 13, penultimate paragraph), or that the disclosure is somehow enabling for SNP analysis wherein the source of the DNA is from "the genome of mammals, including humans, non-human primates, domestic animals (such as dogs, cats, etc.), farm animals (such as cattle, sheep, etc.) and other economically important animals," including birds such as chickens and turkeys (specification at page 13, penultimate paragraph), does not rise to the level of an enabling disclosure, but rather constitutes only an invitation to experiment.

For the above reasons, and in the absence of convincing evidence to the contrary, the rejection of claims 34-38, 42-44., and 47-50 under 35 USC 112, first paragraph, is maintained and is also applied against new claims 51-53.

Conclusion

3. No claim is allowed.

4. Rejections and objections which appeared in the prior Office action and which were not repeated hereinabove, have been withdrawn.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978 and whose e-mail

address is bradley.sisson@uspto.gov. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The fax phone numbers for Group 1630 are (703) 305-3014 and (703) 305-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist for Technology Center 1600 whose telephone number is (703) 308-0196.

B. L. Sisson

BRADLEY L. SISSON
PRIMARY EXAMINER
GROUP ~~1800~~ 1634

11-22-98